NC DEPARTMENT OF HEALTH AND HUMAN SERVICES

NC State Health Director's Statewide Standing Order
for Administering Pfizer-BioNTech Covid-19 Bivalent Vaccine in Individuals 5 years of age or older April 21, 2023

Purpose: To reduce morbidity and mortality from coronavirus disease 2019 (COVID-19) by vaccinating persons who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP) and to administer Pfizer-BioNTech (herein-after Pfizer vaccines) to persons who meet criteria set-forth by the Food and Drug Administration in accordance with FDA Emergency Use Authorization.

Policy: This standing order authorizes any North Carolina healthcare provider, in accordance with the conditions of their licensure, or pursuant to orders issued under North Carolina Session Law 2022-74, Sec. 9G.7.(a)-(e) or as a covered person under the federal PREP Act functioning as vaccinating providers (collectively "vaccinators") to administer COVID-19 Vaccines authorized by the FDA per conditions of this order.

Note: On April 18, 2023, the FDA rescinded the EUA of all mRNA monovalent COVID-19 vaccine products. This decision was based on data reflecting the overall improved effectiveness of the bivalent vaccines vs. monovalent vaccines and the fact that the most prominently circulating SARS- CoV2 strains are of Omicron BA.4/BA.5 lineage. This action also simplifies the vaccination schedule for most individuals.

COVID-19 Vaccination	
Condition/ Situation:	**ALERT**: Pfizer monovalent COVID-19 vaccine is no longer authorized in this age group. All individuals 5 years of age and older are eligible for this vaccine. Dosing is based on vaccine history, age, and immunocompromised status. Booster doses are not authorized with this new schedule. Patients present requesting vaccination will receive, with appropriate written consent from an authorized caregiver, as applicable: ➢ **Unvaccinated Individuals:** Administer a single dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent vaccine. ➢ **Individuals who have only received Pfizer-BioNTech monovalent COVID-19 Vaccine or other mRNA monovalent vaccine:** Administer one dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent at least 2 months after previous vaccine. ➢ **Individuals 65 years of age and older who have received one dose of a bivalent COVID-19 vaccine:** Administer one dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent at least 4 months after the dose of bivalent vaccine. ➢ **Immunocompromised individuals 5 years of age and older who have received one dose of a bivalent COVID-19 vaccine:** Administer one dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent at least 2 months following the previous dose of bivalent vaccine. Refer to Healthcare Provider if an additional dose is requested to obtain an individual medical order.

Individuals 5 years of age and older previously vaccinated with 1 or more doses of a monovalent COVID-19 vaccine[4] (2.3)

Age	Pfizer-BioNTech COVID-19 Vaccine, Bivalent Vial Cap and Label Border Color	Dosing Regimen, Dose and Schedule
5-11y	Orange	Single dose, 0.2 mL ≥2 months after monovalent COVID-19 vaccine
12-64y	Gray	Single dose, 0.3 mL ≥2 months after monovalent COVID-19 vaccine
≥65y	Gray	Single dose, 0.3 mL ≥2 months after monovalent COVID-19 vaccine One additional dose, 0.3 mL, may be administered ≥4 months after first dose of an authorized bivalent COVID-19 vaccine

[4] Monovalent refers to a COVID-19 vaccine that contains or encodes the spike protein of only the Original SARS-CoV-2.

For individuals with certain kinds of immunocompromise[5] 5 years of age and older, a single additional age-appropriate dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent may be administered at least 2 months following the initial dose of a bivalent COVID-19 vaccine; additional age-appropriate doses of Pfizer-BioNTech COVID-19 Vaccine, Bivalent may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.

Assessment Criteria	
Assessment Criteria	Patients 5 years of age and older shall be vaccinated with Pfizer BioNTech COVID-19 Vaccine, Bivalent based on: 1. The conditions/situations of this order (see above). 2. The patient is presenting for first dose or subsequent dose/s of a bivalent COVID-19 vaccine. 3. Availability of age-appropriate Pfizer-BioNTech COVID-19 Vaccine, Bivalent formulations.
Plan of Care	
Actions	**Patient Education and Data Collection** Prior to patients receiving the COVID-19 vaccine, the vaccinator or designee (if delegation permitted by licensure and/or law) shall provide anticipatory guidance regarding vaccination to the patient, which at a minimum shall include: 1. Review CDC Pre-Vaccination Checklist for COVID-19 Vaccine. 2. Fact Sheet for Recipients and Caregivers About Pfizer-BioNTech COVID-19 Vaccine for 5 years of age and older.

3. Patient's authorized caregiver should consult primary care or other health care provider if they have questions regarding which COVID-19 vaccine they should receive. Refer to Interim Clinical Considerations for latest vaccine information.

Pfizer COVID-19 Vaccine 5 years of age and older:

Administration Procedures

1. Review Interim Clinical Considerations for Use of COVID-19 Vaccines Currently Approved or Authorized in the United States.
2. Pfizer COVID-19, bivalent vaccine for pediatric patients 5 years through 11 years of age is supplied in an ORANGE **CAP** formulation. No other formulation should be used in this population. The vaccinator shall be familiar with procedures for preparation, storage & handling of the Pfizer formulation they are using. Review the Fact Sheet for Healthcare Providers Administering Pfizer Vaccine for 5 years of age and older
3. Pfizer COVID-19 vaccine for patients 12 years through 64 years of age is supplied in a **GRAY CAP** formulation. No other formulation should be used in this population. The vaccinator shall be familiar with procedures for preparation, storage & handling of the Pfizer formulation they are using.
4. Pfizer COVID-19 vaccine for patients 65 years of age and older is supplied in a **GRAY CAP** formulation. No other formulation should be used in this population. The vaccinator shall be familiar with procedures for preparation, storage & handling of the Pfizer formulation they are using.
5. Appropriate medical treatment and clinical staff able to manage immediate allergic reactions must be immediately available in the event an acute anaphylactic reaction occurs following administration of mRNA COVID-19 vaccine.
6. A medical provider, defined as a physician, physician assistant, nurse practitioner, or a pharmacist authorized to order COVID-19 vaccines by the PREP Act must be accessible to provide medical supervision of the vaccination site/service, to assess and evaluate individuals who present with contraindications or precautions to vaccination, and to answer questions or address problems with carrying out this standing order. This may be telephone or virtual accessibility.
7. Review *Special Circumstances*, *Precautions*, *Contraindications*, and *Criteria or Circumstances for Notifying Medical Provider* sections of this standing order **before** administering the COVID-19 vaccine. More information is available at this site - CDC COVID-19 Vaccines for Special Populations.
8. Following the current *CDC Pre-Vaccination Checklist for COVID-19 Vaccines*, instruct patients accordingly or consult with overseeing provider.
    a. The pre-vaccination checklist shall be followed with the following exception: COVID-19 vaccination should ***not*** be deferred in

patients who received monoclonal antibody treatment or convalescent plasma.

9. When vaccinating a minor with **Pfizer COVID-19 vaccine,** consent must be obtained from the patient's authorized caregiver prior to administration per conditions of this order, agency policy and in accordance with NC General Statute 90-21.13 and Minor Consent Law and Session Law 2021-110. (Section 9, a1)
10. Personal Protective Equipment: Before administering the COVID-19 vaccination, don appropriate personal protective equipment (PPE) per CDC guidelines for COVID-19 vaccinations to protect against the transmission of COVID-19.

Vaccine Product & Preparation:

Vaccine product: Ensure the appropriate Pfizer formulation, based on age is selected. In general, the same mRNA vaccine product should be used for all doses in the primary series. Discard all formulations 12 hours after first puncture. See CDC guidance for exceptional situations.

Preparation: Prepare vaccine, observing aseptic technique, according to the manufacturer's instructions. Follow manufacturer's guidance for storing/handling prepared vaccine. When using the age-appropriate formulation, refer to Fact Sheet for Healthcare Providers Administering Pfizer Vaccine for 5 years of age and older. Once the vial is punctured it must be discarded after 12 hours.

Dosing:

1. Administer age-appropriate dose of Pfizer COVID-19, bivalent vaccine to patients (see chart below). **Diluent is required.**
2. When a patient inadvertently receives an incorrect/inappropriate dose of COVID-19 vaccine, review Appendix D. Vaccine administration errors and deviations, and take action as directed.

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Age	Pfizer-BioNTech COVID-19 Vaccine, Bivalent Vial Cap and Label Border Color	Dosing Regimen, Dose and Schedule
5-11y	Orange	Single dose, 0.2 mL ≥2 months after monovalent COVID-19 vaccine
12-64y	Gray	Single dose, 0.3 mL ≥2 months after monovalent COVID-19 vaccine
≥65y	Gray	Single dose, 0.3 mL ≥2 months after monovalent COVID-19 vaccine One additional dose, 0.3 mL, may be administered ≥4 months after first dose of an authorized bivalent COVID-19 vaccine

[4] Monovalent refers to a COVID-19 vaccine that contains or encodes the spike protein of only the Original SARS-CoV-2.

For individuals with certain kinds of immunocompromise[5] 5 years of age and older, a single additional age-appropriate dose of Pfizer-BioNTech COVID-19 Vaccine, Bivalent may be administered at least 2 months following the initial dose of a bivalent COVID-19 vaccine; additional age-appropriate doses of Pfizer-BioNTech COVID-19 Vaccine, Bivalent may be administered at the discretion of the healthcare provider, taking into consideration the individual's clinical circumstances.

Timing:

All recommended doses of Pfizer shall be administered as close to the recommended interval as possible. Doses that are given up to 4 days (the "grace period") before the recommended interval are valid and should not be repeated. The 4-day grace period shall not be used to prospectively schedule or administer a COVID-19 vaccine dose earlier than recommended. (See interval tables above)

Administration:

Route of Administration: Administer Pfizer- BioNTech COVID-19 Vaccine, Bivalent by intramuscular (IM) injection in the deltoid muscle of the arm to patients 5 years of age and older. If contraindications exist to using the deltoid, the anterolateral thigh also can be used.

Needle Gauge: Changing needles between drawing up vaccine from a vial and injecting it into a patient is not necessary unless the needle has been damaged, contaminated, or if the needle used to draw up the vaccine is not the correct size for the patient based on their

reported age or weight. Patients may self-report their weight for needle selection purposes. See needle sizing chart below:

Age of Patient	Needle Gauge	Needle Length	Injection Site
5-10 years old	16-25 mm	*5/8-1 inch	Deltoid muscle
	25-32 mm	1-1.25 inches	Anterolateral thigh
11 years old	16-25 mm	*5/8-1 inch	Deltoid muscle
	25-38 mm	1-1.25 inches	Anterolateral thigh

Sex and Weight of Patient	Needle Gauge	Needle Length	Injection Site*
Female or male fewer than 130 lbs.	22–25	5/8 ** –1"	Deltoid muscle of arm
Female or male 130–152 lbs.	22–25	1"	Deltoid muscle of arm
Female 152–200 lbs.	22–25	1-11/2"	Deltoid muscle of arm
Male 153–260 lbs.	22–25	1-11/2"	Deltoid muscle of arm
Female 200+ lbs.	22–25	11/2"	Deltoid muscle of arm
Male 260+ lbs.	22–25	11/2"	Deltoid muscle of arm

* Alternatively, the anterolateral thigh also can be used.

** Some experts recommend a 5/8-inch needle for men and women who weigh less 130 pounds. If used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

Multiple vaccinations: If multiple vaccines are administered at a single visit, administer each injection in a different injection site following guidance in the CDC Interim Clinical Considerations - COVID-19 vaccine and coadministration with other vaccines.

Bleeding Risk: Patients with blood disorders or who are on blood thinners: administer the vaccine using a 23 gauge or smaller caliber needle, followed by firm pressure on the site, without rubbing, for at least 2 minutes.

Documentation:

1. Patient or caregiver attestation to severe or moderate immunocompromise should be done within the notes section in CVMS or comparable section of an EHR or other documenting systems.
2. **CVMS/NCIR**: Document vaccine record in CVMS or NCIR **within 24 hours** after vaccine administration per system guidelines found at: https://immunize.nc.gov/providers/covid-19training.htm. If vaccine is

	documented in the EHR within 24 hours, providers have **no more than 72 hours** from administration to also enter data in CVMS or NCIR. Determining whether to document in CVMS versus NCIR should occur according to site protocol; it is not necessary to document in both systems. 3. **Electronic Medical Record**: If necessary for billing or other purposes, document patient COVID-19 vaccination in agency electronic medical record per agency policy. 4. Provide vaccine recipients and/or their legal representative COVID-19 Vaccination Record Card indicating the vaccine dose number, product name/manufacturer, lot number, date of vaccination, name/location of vaccinator and clinic site. 5. Counsel when and how patient needs to schedule return appointment for additional of COVID-19 vaccine doses, if applicable.
	Pfizer COVID-19 Vaccination Observation and Follow-Up 1. **Post-vaccination Observation**: Nurses, EMS, or other individuals who are trained and supervised by clinical staff shall observe patients post-vaccination for immediate allergic reactions according to the Centers for Disease Control and Prevention guidelines for the following time periods: a. **30 minutes:** • Persons with a history of an immediate allergic reaction of any severity to a non-COVID-19 vaccine • Persons with a history of anaphylaxis due to any cause • People with a contraindication to a different type of COVID-19 vaccine (for example, people with a contraindication to a viral vector vaccine-Janssen/Johnson and Johnson who receive a mRNA vaccine-Pfizer or Moderna/SPIKEVAX) should be observed for 30 minutes following vaccination. • Persons with an immediate (within 4 hours of exposure) non-severe allergic reaction to a COVID-19 vaccine or injectable therapy b. **15 minutes:** All other persons 2. **Anaphylaxis Management**: Be prepared to manage medical emergencies by following your emergency response policies, procedures, and standing orders for any vaccine reaction, which must include appropriate equipment and medications (e.g., epinephrine, diphenhydramine) where vaccines are provided to respond to severe allergic reactions and anaphylaxis. 3. **Syncope:** Be prepared to manage syncope as it may occur in association with administration of injectable vaccines, particularly in adolescents. Procedures should be in place to avoid injury from fainting.
Special Circumstances	**People who received COVID-19 vaccination outside the United States:** The recommendations for people vaccinated outside of the United States depend on the

	vaccine(s) received for the primary series, whether the primary series was completed, and whether a booster dose was received. Refer to Interim Clinical Considerations, Appendix A (People who received COVID-19 vaccine outside the United States) and take action/ consult with medical provider as directed. **Participants in clinical trials within or outside the United States** U.S. trial participants, along with non-U.S.-based participants in the same trial, who received all the recommended primary series doses of a vaccine that is not listed for emergency use by WHO but for which a U.S. data and safety monitoring board or equivalent has independently confirmed efficacy are considered up to date with their COVID-19 vaccines when they have received a **bivalent mRNA dose**. Appendix B. People who received COVID-19 vaccine as part of a clinical trial 1. If clinical trial participants have questions about whether they should receive an additional and/or booster dose outside of the clinical trial, they should consult with their healthcare provider. Clinical trial participants who did not receive all the recommended doses, or who received other vaccines not listed above, should consult with their healthcare provider to determine if they should receive an FDA-approved or FDA-authorized COVID-19 vaccine series.
Follow-up	Adverse events that occur in a recipient following COVID-19 vaccination should be reported to VAERS. Vaccination providers are required by the FDA to report the following that occur after COVID-19 vaccination under BLA or EUA: 1. Vaccine administration errors 2. Serious adverse events 3. Cases of Multisystem Inflammatory Syndrome 4. Cases of COVID-19 that result in hospitalization or death Reporting is encouraged for any other clinically significant adverse event, even if it is uncertain whether the vaccine caused the event. Information on how to submit a report to VAERS is available at https://vaers.hhs.gov or by calling 1-800-822-7967.
Precautions for Use of this Order	1. Persons with a history of an immediate allergic reaction to any other vaccine other than COVID-19 vaccine or to any injectable therapy (i.e., intramuscular, intravenous, or subcutaneous vaccines or therapies [excluding subcutaneous immunotherapy for allergies, i.e., "allergy shots"]). This includes people with a history of an immediate allergic reaction to a vaccine or injectable therapy that contains multiple components, one of which is a COVID-19 vaccine component, even if it is unknown which component elicited the immediate allergic reaction. 2. Persons with a contraindication to one type of a COVID-19 vaccine (e.g., viral vector – Janssen/Johnson and Johnson) have a precaution to another (e.g., mRNA – COMIRNATY/Pfizer or Moderna/SPIKEVAX) because of potential cross-reactive hypersensitivity. Consultation with an allergist-immunologist should be considered prior to vaccination and patients with this precaution should be vaccinated in a health care setting where allergic reactions can be immediately managed and under

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	the supervision of a health care provider experienced in the management of severe allergic reactions. 3. Patient self-reported moderate to severe acute illness. 4. Persons with a precaution to vaccination must be counseled about the unknown risks of experiencing a severe allergic reaction and balance these risks against the benefits of vaccination. 5. Persons with a history of myocarditis or pericarditis. 6. Persons with a history of MIS-C or MIS-A.
Contraindications for Use of this Order	Do not administer the COVID-19 Vaccine to individuals with a history of: - Severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of the vaccine - Immediate allergic reaction of any severity to a previous dose or known (diagnosed) allergy to a component of the vaccine. - See additional guidance: Interim Clinical Considerations, Appendix E: Triage of people with history of allergies or allergic reactions
Criteria or Circumstances for Notifying Medical Provider	1. Allergic reaction: Call 911, implement medical emergency protocols and immediately notify the medical provider providing clinical supervision of the vaccination site/service. 2. Patient reports a precaution for the vaccine. 3. COVID-19 vaccine history cannot be determined or is not available. 4. Patients vaccinated with COVID-19 vaccines not authorized or approved in the US. 5. Patients vaccinated with active COVID-19 vaccine as part of a clinical trial. 6. Patient reports they are a HCT or CAR-T cell recipient. These patients may need revaccination, dependent on when the transplant or therapy occurred. 7. Notify the Medical Provider from the organization providing clinical supervision of the vaccination site/service at any time there are questions or problems with carrying out this standing order. Note: Healthcare providers or health departments in the United States can request a consultation from CISA COVID vax for a complex COVID-19 vaccine safety question that is (1) about an individual patient residing in the United States or vaccine safety issue and (2) not readily addressed by CDC or Advisory Committee on Immunization Practices (ACIP) guidelines.

Approved by: __ CTilson

Date Signed: 4-21-23_____

Elizabeth Cuervo Tilson
NPI: 1760540421

This standing order is effective immediately and authorizes any North Carolina healthcare provider, in accordance with the conditions of their licensure, or pursuant to orders issued under North Carolina Session Law 2022-74, Sec. 9G.7.(a)-

(e). or as a covered person under the federal PREP Act functioning as vaccinating providers (collectively "vaccinators") to administer COVID-19 Vaccines authorized by the FDA per conditions of this order.